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ATTY. DOCKET: 17328.	SERIAL NO.: 09/550,371 10/630, 5-87
APPLICANT: AOKI, ET AL.,	TITLE: METHOD FOR TREATING PAIN BY PERIPHERAL ADMINISTRATION OF A NEUROTOXIN
FILING DATE: April 14, 2000	GROUP: /653

#### **UNITED STATES PATENTS**

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
CMK	AA	6,113,915	9/5/00	AOKI	424	236	•

#### FOREIGN PATENT DOCUMENTS

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#### OTHER ART

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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#### SUPPLEMENTAL LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 17328 (BOT).	SERIAL NO.: 09/550,371 19/639 587
APPLICANT: AOKI, et al.	TITLE: METHOD FOR TREATING PAIN BY PERIPHERAL ADMINISTRATIONOF A NEUROTOXIN
FILING DATE: APRIL 14, 2000	GROUP: 1653

U.S. PATENT DOCUMENTS

•EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
CMK	AA	AA 6,113,915	9/5/00	AOKI	424		
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FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (ves/n )
CHIC	BA	WO 97/34624	9/25/97	PCT	,		
$TT^{}$	BB	WO 96/33273	10/24/96	РСТ			
CHK	BC	WO 95/30431	11/16/95	PCT			_

#### OTHER ART

(Including Author, Title, Date, Pertinent Pages, etc.)

OYK	CA	Guyer, B., Mechanism of botulinum toxin in the relief of chronic pain, Current Review of Pain, 1999, 3:427-431, XP-001031379
	СВ	Carruthers, A., et al., Improvement of tension-type headache when treating wrinkles with botulinum toxin A injections, Headache, Oct. 1999:39:662-665, XP-001031356
	CC	Diaz, J., et al., Management of post-thoracotomy pseudoangina and myofascial pain with botulinum toxin, Anesthesiology, V 91, No. 3, Sep 1999, pp. 877-879, XP-001031347
	CĐ	Silberstein, S., et al., Botulinum toxin type A as a migraine preventive treatment, Headache 2000:40:445-450, XP-002182692
CMK	CE	Gobel, H., et al., Evidence-based medicine: botulinum toxin A in migraine and tension-type headache, Journal of Neurology, 2001 248 Supp 1: I/34-I/38, XP-002182693
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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## LIST OF ART CITED BY APPLICANT

ATTY. DOCKET:	17328(AP)	SERIAL NO.: 09/550,371 10/639,5-87
APPLICANT:	Aoki et al.	TITLE: METHOD FOR TREATING PAIN BY PERIPHERAL ADMINISTRATION OF A NEUROTOXIN
FILING DATE:	04/14/2000	GROUP: -1646 /65}

# **U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
CMK	AA	6,063,768	5/16/00	FIRST			
	AB						

## FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
BA						
BB						

## **OTHER ART**

(Including Author, Title, Date, Pertinent Pages, etc.)

C	CMK CA		Cheng, Guang-Shing; Botox, Dermabrasion Treated Facial Leiomyomas; Skin & Allergy News 2000;31(3):16.
	T	СВ	First, E. et al.; Painful Cervical Dystonia: Response to Treatment with Botulinum Toxin; Mov Disord 1998;13(Suppl2):100.
_		CC	Guyer, Barry M.; Mechanism of Botulinum Toxin in the Relief of Chronic Pain; Curr Rev Pain 1999;3(6):427-431.
		CD	Li, Yan, et al.; A Single Mutation in the Recombinant Light Chain of Tetanus Toxin Abolishes Its Proteolytic Activity and Removes the Toxicity Seen after Reconstitution with Native Heavy Chain; Biochemistry 1994, 33, 7014-7020.
		CE	Schantz, Edward J., et al.; Properties and Use of Botulinum Toxin and Other Microbial Neurotoxins in Medicine; Microbiological Reviews Mar. 1992, pp. 80-99, Vol. 56, No. 1.
		CF	Tarsy, Daniel, et al.; Painful Cervical Dystonia: Clinical Features and Response to Treatment With Botulinum Toxin; Mov Disord 1999;14(6):1043-1045.
Ci	1 <u>E</u>	CG	Zhou, Liqing, et al.; Expression and Purification of the Light Chain of Botulinum Neurotoxin A: A Single Mutation Abolishes Its Cleavage of SNAP-25 and Neurotoxicity after Reconstitution with the Heavy Chain; Biochemistry 1995, 34, 15175-15181.
		СН	

EXAMINER	ch_	DATE CONSIDERED	4/29/05

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Sheet	1	of	4

## LIST OF ART CITED BY APPLICANT

ATTY. DOCKET:	17328(AP)	SERIAL NO.: 10/630, 5-87		
APPLICANT: AOKI et al.		TITLE: METHOD FOR TREATING PAIN BY PERI- PHERAL ADMINISTRATION OF A NEUROTOXIN		
FILING DATE:	(Herewith)	GROUP: 1653		

## **U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
CMK	AA	5,714,468	2/3/98	BINDER			
7	AB	5,766,605	6/16/98	SANDERS ET AL.			
CMK	AC	5,989,545	11/23/99	FOSTER ET AL.			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
CMK	BA	94/15629	7/21/94	PCT			
7	BB	96/33273	10/24/96	PCT			
	BC	98/07864	2/26/98	PCT			
CMK	BD	99/17806	4/15/99	PCT			

# OTHER ART

(Including Author, Title, Date, Pertinent Pages, etc.)

CMK CA		Barwood, Shane, et al.; Analgesic Effects of Botulinum Toxin A: A Randomized, Placebo- Controlled Clinical Trial; Developmental Medicine & Child Neurology, 2000; 42:116-121
	СВ	Bigalke, H., et al.; Botulinum A Neurotoxin Inhibits Non-Cholinergic Synaptic Transmission in Mouse Spinal Cord Neurons in Culture; Brain Research, 360 (1985); 318-324.
	CC	Bigalke, H., et al.; Tetanus Toxin and Botulinum A. Toxin Inhibit Release and Uptake of Various Transmitters, as Studied with Particulate Preparations from Rat Brain and Spinal Cord; Naunyn-Schmiedeberg's Arch. Pharmacol (1981); 316:244-251.
	CD	Cheshire, et al.; Botulinum Toxin in the Treatment of Myofascial Pain Syndrome; Pain, 1994; 59(1):65-9.
CMK	CE	DiStefano, P. S., et al.; Receptor Mediated Retrograde Axonal Transport of Neurotrophic Factors is Increased After Peripheral Nerve Injury; Progress in Brain Research (1994); Vol. 103; Chapter 4; 35-42.

EXAMINER DATE CONSIDERED 1/29/05

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Sheet	2	of	4

# LIST OF ART CITED BY APPLICANT

ATTY. DOCKET:	17328(AP)	SERIAL NO.: 10/630,587
APPLICANT:	AOKI et al.	TITLE: METHOD FOR TREATING PAIN BY PERI- PHERAL ADMINISTRATION OF A NEUROTOXIN
FILING DATE:	(Herewith)	GROUP: 1683

OTHER ART (Continued)
(Including Author, Title, Date, Pertinent Pages, etc.)

	CMK	CF	Dixon, W. J.; Efficient Analysis of Experimental Observations; Ann. Rev. Pharmacol. Toxicol. (1980); 20:441-462.
		CG	Dubuisson, D., et al.; The Formalin Test: A Quantitative Study of the Analgesic Effects of Morphine, Meperidine, and Brain Stem Stimulation in Rats and Cats; Pain (1977); 4:161-174.
		СН	Duc, C., et al.; Ultrastructural Localization of SNAP-25 Within the Rat Spinal Cord and Peripheral Nervous System; The Journal of Comparative Neurology (1995); 356:152-163.
		CI	Fauci, A.S., et al. (Editors); <u>Harrison's Principles of Internal Medicine</u> , 14 <sup>th</sup> Edition (1998); McGraw-Hill; 2064-2065.
	1.	CJ	Garner, C.G., et al.; Time Course of Distant Effects of Local Injections of Botulinum Toxin; Movement Disorders; Vol. 8, No. 1; 1993.
		CK	Habermann, E.; Inhibition by Tetanus and Botulinum A Toxin of the Release of ( <sup>3</sup> H)noradrenaline and ( <sup>3</sup> H)GABA from Rat Brain Homogenate; Experientia 44 (1988); 224-226.
		CL	Habermann, E.; I-Labeled Neurotoxin from Clostridium Botulinum A: Preparation, Binding to Synaptosomes and Ascent to the Spinal Cord; Naunyn Schmiedeberg's Arch. Pharmacol.; 281, 47-56 (1974).
		СМ	Habermann, E., et al.; Tetanus Toxin and Botulinum A and C Neurotoxins Inhibit Noradrenaline Release from Cultured Mouse Brain; Journal of Neurochemistry; Vol. 51; No. 2 (1988); 522-527.
		CN	Hagenah, R., et al.; Effects of Type A Botulinum Toxin on the Cholinergic Transmission at Spinal Renshaw Cells and on the Inhibitory Action at Ia Inhibitory Interneurones; Naunyn-Schmiedeberg's Arch. Pharmacol.; 299, 267-272 (1977).
		СО	Halpern, J.L., et al.; Neurospecific Binding, Internalization, and Retrograde Axonal Transport; Date Unknown; pp. 221-241.
	-	СР	Johnson, E., et al.; Biomedical Aspects of Botulinum Toxin; J. ToxicolToxin Reviews; Feb. 18, 1999; 18(1):1-15.
CT	1/	CQ	Jung, H. H., et al.; Expression of Neurotransmitter Genes in Rat Spinal Motoneurons After Chemodenervation with Botulinum Toxin; Neuroscience (1997); Vol. 78, No. 2; 469-479.

		4/29/
EXAMINER OF COLOR	DATE CONSIDERED _	105

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Sheet	3	of	4

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ATTY. DOCKET:	17328(AP)	SERIAL NO.: 10/630, 587
APPLICANT:	AOKI et al.	TITLE: METHOD FOR TREATING PAIN BY PERI- PHERAL ADMINISTRATION OF A NEUROTOXIN
FILING DATE:	(Herewith)	GROUP: /653

OTHER ART (Continued)
(Including Author, Title, Date, Pertinent Pages, etc.)

(	C1K	CR	Kim, S. H., et al.; An Experimental Model for Peripheral Neuropathy Produced by Segmental Spinal Nerve Ligation in the Rat; Pain, 50 (1992); 355-363.
		CS	Li et al.; Biochemistry; 33:7014-7020 (1994).
		СТ	Mochida, S., et al.; Impairment of Syntaxin by Botulinum Neurotoxin C <sub>1</sub> or Antibodies Inhibits Acetylcholine Release but not Ca <sup>2+</sup> Channel Activity; Neuroscience (1995); Vol. 65; No. 3; 905-915.
		CU	Naumann, et al.; Botulinum Toxin Type A in the Treatment of Focal, Axillary and Palmar Hyperhidrosis and Other Hyperhidrotic Conditions; European Journal of Neurology, 1999; Vol. 6(suppl4):S3-S10 and S111-S115.
		CV	Nelson, P.G., et al.; Mouse Spinal Cord in Cell Culture. IV. Modulation of Inhibitory Synaptic Function; Journal of Neurophysiology; Vol. 40, No. 5; Sept. 1977; 1178-1187.
CW Osen-Sand, A., et al.; Inhibition of Axonal Growth by SNAP-25 Antisense O		Osen-Sand, A., et al.; Inhibition of Axonal Growth by SNAP-25 Antisense Oligonucleotides in vitro and in vivo; Nature; 29 July 1993; Vol. 364; 445-448.	
		CX	Pearce, L. B., et al.; Pharmacologic Characterization of Botulinum Toxin for Basic Science and Medicine; Toxicon (1997); Vol. 35, No. 9; 1373-1412.
		CY	Ragona, et al.; Management of Parotid Sialocele with Botulinum Toxin; Laryngoscope, 109:August 1999; p. 1344-36
		CZ	Ransom, B.R., et al.; Mouse Spinal Cord in Cell Culture. I. Morphology and Intrinsic Neuronal Electrophysiologic Properties; Journal of Neurophysiology; Vol. 40, No. 5; Sept. 1977; 1132-1150.
		DA	Ransom, B.R., et al.; <i>Mouse Spinal Cord in Cell Culture. II. Synaptic Activity and Circuit Behavior</i> ; Journal of Neurophysiology; Vol. 40, No. 5; Sept. 1977; 1151-1162.
		DB	Ransom, B.R., et al.; Mouse Spinal Cord in Cell Culture. III. Neuronal Chemosensitivity and its Relationship to Synaptic Activity; Journal of Neurophysiology; Vol. 40, No. 5; Sept. 1977; 1163-1177.
		DC	Rees, H., et al.; Do Dorsal Root Reflexes Augment Peripheral Inflammation?; Neuro Report; Vol. 5, No. 7; 21 March 1994; 821-824.
CM	K	DD	Sanchez-Prieto, J., et al.; Botulinum Toxin A Blocks Glutamate Exocytosis from Guinea-Pig Cerebral Cortical Synaptosomes; Eur. J. Biochem. (1987); 165:675-681.

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EXAMINER	Ohe-		DATE CONSIDERED	1/05

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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FILING DATE:	(Herewith)	GROUP: /653

OTHER ART (Continued)
(Including Author, Title, Date, Pertinent Pages, etc.)

ONK	DE	Shantz, E.J., et al.; Properties and Use of Botulinum Toxin and Other Microbial Neurotoxins
		in Medicine; Microbiol Rev.; 56:80-99 (1999).
1	DF	Simpson, L.; Botulinum Toxin: Potent Poison, Potent Medicine; Hospital Practice; April 15,
	1	1999; 34(4):87-91.
	DG	Singh, B.R.; Critical Aspects of Bacterial Protein Toxins; Natural Toxins II (1996); Plenum
		Press, New York; pp. 63-84.
	DH	Tonra, J. R., et al.; Axotomy Upregulates the Anterograde Transport and Expression of
1 1	1	Brain-Derived Neurotrophic Factor by Sensory Neurons; The Journal of Neuroscience; June
		1, 1998; 18(11):4374-4383.
	DI	Tsuda, M., et al.; In vivo Pathway of Thermal Hyperalgesia by Intrathecal Administration of
1	i	α, β-methylene ATP in Mouse Spinal Cord: Involvement of the Glutamate-NMDA Receptor
	ŀ	System; Br. J. Pharmacol (1999); 127(2):449-456.
	DJ	Wiegand, H., et al.; The Action of Botulinum A Neurotoxin on the Inhibition by Antidromic
1		Stimulation of the Lumbar Monosynaptic Reflex; Naunyn-Schmiedeberg's Arch. Pharmacol.
	i	(1977); 298:235-238.
	DK	Wiegand, H., et al.; I-Labelled Botulinum A Neurotoxin: Pharmacokinetics in Cats After
		Intramuscular Injection; Nauyn-Schmiedeberg's Arch. Pharmacol.; 292, 161-165 (1976).
T	DL	Williamson, L. C., et al.; Clostridial Neurotoxins and Substrate Proteolysis in Intact
	<u> </u>	Neurons; The Journal of Biological Chemistry; Mar. 29, 1996; Vol. 271:13; 7694-7699.
	DM	
1 1	1 .	Neurotransmitter Release from Mammalian Spinal Cord Cells in Culture; Journal of
		Neurochemistry; 1992; Vol. 59:6; 2148-2157.
	DN	Willis, W. D.; Pain; The Rat Nervous System; Second Edition; 1995; Academic Press, Inc.;
		pages 725-750.
	DO	Woolf, C. J., et al.; Neuropathic Pain: Aetiology, Symptoms, Mechanisms, and Management;
		The Lancet; June 5, 1999; Vol. 353; 1959-1964.
	DP	Yaksh, T. L., et al.; Chronic Catheterization of the Spinal Subarachnoid Space; Physiology &
		Behavior (1976); Vol. 17:1031-1036.
OMK	DQ	Zhou et al., Biochemistry; 34:15175-15181 (1995).
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